



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,483	10/16/2001	Dirk Boecker	10003016	6038

7590 07/16/2003
AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
----------	--------------

3736

DATE MAILED: 07/16/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,483

Applicant(s)

BOECKER ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 1 - 5, 8 - 10, 12 - 20 and 22 - 41 is/are rejected.
- 7) ☒ Claim(s) 6, 7 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 29 recites the limitation "said transmitter" in line 1. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 37 recites the limitation "said standard port" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 5, 8 – 10, 12 – 20, 22 – 26, 29 and 32 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,772,586 to Heinonen et al.

In regards to claims 1 – 5, 8, 9, 12 – 20, 22 and 32 – 39, Heinonen et al. discloses applicant's claimed invention(Figure 2 – 4) including a sampling module comprising a lancet (19), a driving mechanism (Col. 5, lines 20 – 22), and a sample port (Col. 6, lines 2 – 3) for receiving body fluid from a punctured tissue; an assay sensor module (Col. 5, line 66 – Col. 6, line 6) housed in a

Art Unit: 3736

cartridge, the cartridge having an interface with the sample port and a passageway to transport the body fluid to at least one assay sensor (Col. 5, line 66 – Col. 6, line 6); and a communication module adapted to communicate with an information management system (Col. 3, line 65 – Col. 4, line 15). The communication module has a radio frequency transmitter to transfer information to a remote location and a receiver to communicate with a remote database (Col. 2, lines 47 – 50; Col. 4, lines 28 – 44). The analytical detector module is adapted to couple with the cartridge via standard interface (Col. 4, lines 63 – 67). The information storage unit can store information locally (Col. 5, lines 53 – 58). The information management system is a centralized means for collecting and processing information. Historical information can be displayed locally (Col. 5, lines 53 – 58). The information system comprises a system for brokering medical data and a system for patient management (Col. 4, lines 45 – 53). The communication module has at least one of the following: a processor, display, RF chip, antenna, operating system, RAM DRAM, or a PCMCIA interface.

In regards to claims 10, 23 – 26 and 29, Heinonen et al. discloses applicant's claimed method including obtaining body fluid from a tissue punctured with a lancet driven by a driving mechanism outward from a cartridge by a lancet driver (Col. 5, lines 21 – 27); housing the fluid in a cartridge having an assay sensor module (Col. 5, line 66 – Col. 6, line 66); position the cartridge in an analytical detector module; obtaining information from the analytical detector module; displaying the information locally on a display (Col. 5, lines 53 – 58); and transferring the information to a remote location via a communication module (Col. 3, line 65 – Col. 4, line 44). Heinonen et al. discloses a plurality of assay sensors, each performing the same analysis on the body fluid (Col. 5, lines 27 – 29). The communication module has a transmitter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 27, 28, 30, 31, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,586 to Heinonen et al.

In regards to claims 27 and 28, Heinonen et al. discloses a plurality of assay sensors for providing analysis for glucose. Heinonen et al. fails to teach performing a variety of different analysis on the body fluid. Heinonen et al. does disclose that other measurements could be performed in addition to the monitoring of glucose (Col. 3, lines 59 – 64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the assay sensors as disclosed by Heinonen et al. to perform a variety of different analysis in order to expand the capabilities of the device and to allow better patient monitoring.

In regards to claims 30, 31, 40 and 41, Heinonen et al. discloses a lancet being driven by a driver (Col. 5, lines 21 – 22), but fails to disclose the driver being an electromechanical or an electrical driver. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the mechanical driver as disclosed by Heinonen et al. with an electromechanical or an electrical driver as desired to better control the lancing process.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 3736

Allowable Subject Matter

10. Claims 6, 7 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claim 21 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.



JMLF
July 14, 2003



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700